REMARKS

Claims 16-17 are pending in the application.

The Office Action summary indicates that claims 17-18 are pending in the application and that claims 17-18 are rejected. However, claims 16 and 17 are the pending claims. Applicants believe that the Office Action summary sheet may be in error since the Examiner appears to recognize that claims and 16 are 17 are pending in referring to these claims in the body of the Action. Applicants respectfully request clarification for the record.

Claims 16 and 17 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Kita et al. (CA 2086565) in view of Salim (US 4,945,094) (hereinafter Kita CA '565 and US '094, respectively).

The Examiner relies on Kita CA '565 as disclosing oral administration of tranexamic acid and ascorbic acid capable of effectively curing pigmentation. The Examiner recognizes that Kita CA '565 does not disclose the use of L-cysteine and relies on Salim as disclosing compositions used for improving the condition of skin, including cysteine as a preferable agent in both D and L individual isomers and enantiomers, which can be administered orally. According to the Examiner, it would have been obvious to one of ordinary skill in the art to add cysteine as taught by Salim into the composition of Kita CA '565 since Salim teaches that cysteine has been found to improve the skin in various ways including healing of wounds and protection against non-mechanical injury from chemical materials and against degeneration from other causes including aging.

Applicants traverse the rejection.

Applicants have previously pointed out that Kita CA '565 teaches away from the use of vitamin C derivatives, kojic acid, tranexamic acid, etc. and drugs for internal use containing vitamin C, L-cysteine, glutathione, tranexamic acid, etc., in stating that none of these drugs shows a sufficient effect in a short time. Therefore, one of ordinary skill in the art would not have been motivated to add L-cysteine or any of the other drugs mentioned in the "Background of the Invention" section to the composition of Kita CA '565. Specifically, in view of the teaching of Kita CA '565 that L-cysteine is one of the drugs that was not shown to have a sufficient effect, one of ordinary skill in the art would not have been motivated to specifically add L-cysteine to the combination of tranexamic acid and ascorbic acid taught by Kita CA '565 or to substitute L-cysteine for ascorbic acid in the composition of Kita CA '565.

In the "Response to Arguments", the Examiner states that the present claims are drawn to a composition of matter and not a method of treatment, therefore the fact that the use of tranexamic acid and ascorbic acid may not show significant effect in a short time does not teach away from them working at all.

However, Applicants respectfully disagree and submit that the present claims are directed to a method of treatment, i.e., "a method of whitening skin".

Further, with respect to the Examiner's assertion that Kita CA '565 does not teach away from the claimed invention, Applicants submit that the Examiner is not considering the proper standard. Obviousness is what the combined teachings of the references would have suggested to those of ordinary skill in the art and the proper inquiry is whether the prior art as a whole suggests the *desirability* of the claimed invention. See MPEP § 2143.01(1) and (II). A disclosure which criticizes, discredits, or otherwise discourages the claimed invention may be a

sufficient teaching away to establish nonobviousness of a claimed invention. See MPEP § 2143.02(VI) quoting *In re Fulton*, 391 F.3d 1195, 1201, 73 USPQ2d 1141, 1146 (Fed. Cir. 2004). In this case, Kita CA '565 does in fact criticize, discredit and discourage the use of vitamin C derivatives, kojic acid, tranexamic acid, etc., and drugs for internal use containing vitamin C, L-cysteine, glutathione, tranexamic acid, etc., in stating that none of these drugs shows a sufficient effect in a short time, particularly since the object of Kita CA '565 is to produce a sufficient skin whitening effect through short-term administration. Therefore, in view of the teaching of Kita CA '565 that L-cysteine is one of the drugs that was not shown to have a sufficient effect, one of ordinary skill in the art would not have been motivated to combine Kita CA '565 and Salim and to specifically add L-cysteine to the combination of tranexamic acid and ascorbic acid taught by Kita CA '565 or to substitute L-cysteine for ascorbic acid in the composition of Kita CA '565.

Moreover, as the present invention is directed to a method of whitening skin, Salim does not remedy the deficiencies of Kita CA '565. Specifically, Salim is not specifically related to skin whitening or pigmentation and Salim does not teach or suggest that the disclosed compositions can be used orally for skin whitening or pigmentation.

Salim discloses a composition for improving skin conditions. But, Salim describes concrete examples of the improvements of skin conditions, such as healing of wounds and ulcers, protection against non-mechanical injury, e.g., from injurious chemical materials, and against degeneration from causes including ageing (cf. lines 45-52 of column l). Example 3(1)-(6) evaluate improving effects on "skin conditions" such as skin erythema, wife dermatitis, skin

ageing, and wrinkles. All of these "skin conditions" are symptoms of the skin surface and do not have relationship with melanin biosynthesis.

Salim does teach oral compositions, but the oral compositions are only used for G.I. treatment. See Examples 5-8 at columns 8 and 9 of Salim.

On the other hand, the present invention relates to whitening, concretely, whitening against pigmentation of the skin. As described in the "Background" section of the specification, pigmentation occurs by the excess deposition of melanin pigments at the skin. The whitening effect of the present invention is exhibited based on the inhibition of melanin pigment deposition (cf. Industrial Applicability of the specification) and thus it is completely different from the improvement of the "skin conditions" mentioned above. Similarly, the effect on pigmentation described in Kita CA '565 is completely different from the improvement of the "skin conditions" described in Salim.

Furthermore, Salim does not specifically teach that the alleged advantages are due to the organic, *in vivo* sulphydryl group releasing agent. Therefore, there is no apparent reason for one of ordinary skill in the art to specifically select the sulphydryl group releasing agent as a single ingredient to add to the composition of Kita CA '565 from the combination of ingredients disclosed in the composition of Salim and to further specifically select cysteine as the sulphydryl group releasing reagent with a reasonable expectation of success.

Although Salim describes an effect of cysteine to improve the "skin conditions", it does not describe an effect on the pigmentation described in Kita CA '565. Accordingly, it was not obvious to one skilled in the art that addition of the composition described in Kita CA '565 to cysteine taught by Salim can show excellent whitening effects.

In other words, because the composition disclosed in Kita CA '565 and cysteine taught by Salim have different skin conditions as the objects for administration (use and application are different). Accordingly, there is no motivation for one skilled in the art to combine Kita CA '565 and Salim.

Even further, Kita CA '565 was published later in time than Salim and Kita CA '565 teaches that conventionally proposed treatments for pigmentation including L-cysteine do not show a sufficient effect in a short time. Accordingly, there is no apparent reason to combine the references with a reasonable expectation of success in achieving the claimed invention, i.e., a method of skin whitening via oral administration. Thus, for at least the reasons set forth above, the present invention is not rendered obvious over the cited art.

Even further, as previously noted, the present invention provides unexpectedly superior effects as previously mentioned. As is clear from the test examples in the specification (Table 1 on page 13), the combination of tranexamic acid and L-cysteine (sample 6) and the combination of tranexamic acid, L-cysteine and ascorbic acid (sample 8) show extremely excellent effect to prevent pigmentation in comparison with the combination of tranexamic acid and L-ascorbic acid (sample 5). On the other hand, since the result of the combination of L-cysteine and ascorbic acid (sample 7) was not excellent, one skilled in the art would not have reasonably expected a composition in which a plural number of compounds are combined, each having an effect to prevent pigmentation, to show an excellent effect to prevent pigmentation. For this additional reason, the present invention is patentable over the cited art.

In view of the above, the method of whitening according to the present invention, which is characterized in that "a combination tranexamic acid and L-cysteine" or "a combination of

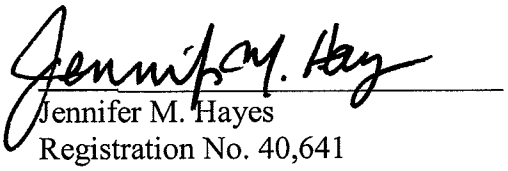
tranexamic acid, L-cysteine and ascorbic acid" is administered, is not obvious to one skilled in the art.

Accordingly, Applicants respectfully request withdrawal of the §103 obviousness rejection.

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,



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